

### **Amendments to the Claims:**

This listing of claims will replace all prior versions, and listings, of claims in the application.

1. (Original) A method of identifying a set of informative genes or markers for a condition comprising a plurality of phenotypic or genotypic characteristics, comprising:

- (a) classifying each of a plurality of samples or individuals on the basis of one or more phenotypic or genotypic characteristics of said condition into a plurality of first classes; and
  - (b) identifying within each of said first classes a first set of genes or markers informative for said condition
- wherein said first set of genes or markers within each of said first classes is unique to said class relative to other first classes.

2-28. (Canceled)

29. (Currently Amended) A method for assigning an individual to one of a plurality of categories in a clinical trial, comprising:

- (a) classifying said individual as ER<sup>-</sup>, *BRCA1*, ER<sup>-</sup>, sporadic; ER<sup>+</sup>, ER/AGE high; ER<sup>+</sup>, ER/AGE low, LN<sup>+</sup>; or ER<sup>+</sup>, ER/AGE low, LN<sup>-</sup>;
- (b) determining for said individual the level of expression of at least two genes for which markers are listed in
  - (b1) Table 1 if said individual is classified as ER<sup>-</sup>, sporadic;
  - (b2) Table 2 if said individual is classified as ER<sup>-</sup>, *BRCA1*;
  - (b3) Table 3 if said individual is classified as ER<sup>+</sup>, ER/AGE high;
  - (b4) Table 4 if said individual is classified as ER<sup>+</sup>, ER/AGE low, LN<sup>+</sup>; or
  - (b5) Table 5 if said individual is classified as ER<sup>+</sup>, ER/AGE low, LN<sup>-</sup>;
- (c) determining, on a computer, whether said individual has a pattern of expression of said at least two genes that correlates with a good prognosis or a poor prognosis; and
- (d) assigning said individual to one category in a clinical trial if said individual has a good prognosis, and assigning said individual to a second category in said clinical trial if said individual has a poor prognosis.

30-41. (Canceled)

42. (Currently Amended) A method for predicting a breast cancer patient as having a good prognosis or a poor prognosis, comprising:

(a) classifying said breast cancer patient into one of the following classes: (a1) ER<sup>-</sup>, sporadic; (a2) ER<sup>-</sup>, *BRCAl*; (a3) ER<sup>+</sup>, ER/AGE high; (a4) ER<sup>+</sup>, ER/AGE low, LN<sup>+</sup>; or (a5) ER<sup>+</sup>, ER/AGE low, LN<sup>-</sup>;

(b) determining a profile comprising measurements of levels of transcripts of, or proteins encoded by, respective genes in a plurality of genes ~~or markers~~ in a cell sample taken from said breast cancer patient, said plurality of genes ~~markers~~ comprising at least two of the genes ~~or markers corresponding to the~~ for which markers are listed in

(b1) Table 1 if said breast cancer patient is classified as ER<sup>-</sup>, sporadic;

(b2) Table 2 if said breast cancer patient is classified as ER<sup>-</sup>, *BRCAl*;

(b3) Table 3 if said breast cancer patient is classified as ER<sup>+</sup>, ER/AGE high;

(b4) Table 4 if said breast cancer patient is classified as ER<sup>+</sup>, ER/AGE low, LN<sup>+</sup>; or

(b5) Table 5 if said breast cancer patient is classified as ER<sup>+</sup>, ER/AGE low, LN<sup>-</sup>; and

(c) classifying, on a computer, said breast cancer patient as having a good prognosis or a poor prognosis based on said profile of said plurality of genes ~~or markers~~,

wherein ER<sup>+</sup> designates a high ER level and ER<sup>-</sup> designates a low ER level, wherein said ER/AGE is a metric of said ER level relative to the age of said patient, and wherein LN<sup>+</sup> designates a greater than 0 lymph nodes status in said patient and LN<sup>-</sup> designates a 0 lymph nodes status in said patient.

43. (Currently amended) The method of claim 42, wherein step (c) is carried out by a method comprising comparing said profile to a good prognosis template and/or a poor prognosis template, and wherein said patient is classified as having a good prognosis if said profile has a high similarity to a good prognosis template or has a low similarity to a poor prognosis template or as having a poor prognosis if said profile has a low similarity to a good prognosis template or has a high similarity to a poor prognosis template, said good prognosis template comprising measurements of levels of transcripts of, or proteins encoded by, respective genes in said plurality of genes ~~or markers~~ that are representative of levels of transcripts of, or proteins encoded by, said genes ~~or markers~~ in a plurality of good outcome patients and said poor prognosis template comprising measurements of levels of transcripts of, or proteins encoded by, respective genes in said plurality of genes ~~or markers~~ that are representative of levels of transcripts of, or proteins encoded by, said genes ~~or markers~~ in a plurality of poor outcome patients, wherein a good outcome patient is a breast cancer patient who has non-

reoccurrence of metastases within a first period of time after initial diagnosis and a poor outcome patient is a patient who has reoccurrence of metastases within a second period of time after initial diagnosis.

44. (Canceled).

45. (Currently amended) The method of claim 43, wherein said profile is an expression profile comprising measurements of a plurality of transcripts in a sample derived from said patient, wherein said good prognosis template comprises measurements of said plurality of transcripts that are representative of expression levels of said transcripts in said plurality of good outcome patients, and wherein said poor prognosis template comprises measurements of said plurality of transcripts that are representative of expression levels of said transcripts in said plurality of poor outcome patients.

46-47. (Canceled).

48. (Previously presented) The method of claim 45, wherein measurement of each said transcript in said good prognosis template is an average of expression levels of said transcript in said plurality of good outcome patients.

49-53. (Canceled)

54. (Previously presented) The method of claim 42, wherein said ER/AGE is classified as high if said ER level is greater than  $c \cdot (AGE - d)$ , and wherein said ER/AGE is classified as low if said ER level is equal to or less than  $c \cdot (AGE - d)$ , wherein  $c$  is a coefficient, AGE is the age of said patient, and  $d$  is an age threshold.

55-57. (Canceled).

58. (Previously presented) The method of claim 42, wherein said individual is ER<sup>-</sup>, sporadic, and said plurality of genes comprises at least two of the genes for which markers are listed in Table 1.

59. (Previously presented) The method of claim 42, wherein said individual is ER<sup>-</sup>, sporadic, and said plurality of genes comprises all of the genes for which markers are listed in Table 1.

60. (Previously presented) The method of claim 42, wherein said individual is ER<sup>-</sup>, *BRCA1*, and said plurality of genes comprises at least two of the genes for which markers are listed in Table 2.

61. (Previously presented) The method of claim 42, wherein said individual is ER<sup>-</sup>, *BRCA1*, and said plurality of genes comprises all of the genes for which markers are listed in Table 2.

62. (Original) The method of claim 42, wherein said individual is ER<sup>+</sup>, ER/AGE high, and said plurality of genes comprises at least two of the genes for which markers are listed in Table 3.

63. (Original) The method of claim 42, wherein said individual is ER<sup>+</sup>, ER/AGE high, and said plurality of genes comprises all of the genes for which markers are listed in Table 3.

64. (Original) The method of claim 42, wherein said individual is ER<sup>+</sup>, ER/AGE low, LN<sup>+</sup>, and said plurality of genes comprises at least two of the genes for which markers are listed in Table 4.

65. (Original) The method of claim 42, wherein said individual is ER<sup>+</sup>, ER/AGE low, LN<sup>+</sup>, and said plurality of genes comprises all of the genes for which markers are listed in Table 4.

66. (Previously presented) The method of claim 42, wherein said individual is ER<sup>+</sup>, ER/AGE low, LN<sup>-</sup>, and said plurality of genes comprises at least two of the genes for which markers are listed in Table 5.

67. (Previously presented) The method of claim 42, wherein said individual is ER<sup>+</sup>, ER/AGE low, LN<sup>-</sup>, and said plurality of genes comprises all of the genes for which markers are listed in Table 5.

68-72. (Canceled).

73. (Original) A microarray comprising a plurality of polynucleotide probes each complementary and hybridizable to a sequence in a different gene listed in any one of Tables 1-5.

74. (Previously presented) A microarray comprising a plurality of polynucleotide probes selected from the group consisting of (i) a plurality of polynucleotide probes each complementary and hybridizable to a sequence in a different gene listed in Table 1, (ii) a plurality of polynucleotide probes each complementary and hybridizable to a sequence in a different gene listed in Table 2, (iii) a plurality of polynucleotide probes each complementary and hybridizable to a sequence in a different gene listed in Table 3, (iv) a plurality of polynucleotide probes each complementary and hybridizable to a sequence in a different gene listed in Table 4, and (v) a plurality of polynucleotide probes each complementary and hybridizable to a sequence in a different gene listed in Table 5.

75-87. (Canceled).

88. (New) A method for assigning a breast cancer patient to one of a plurality of categories in a clinical trial, comprising:

(a) determining if said patient has a good prognosis or a poor prognosis using the method of claim 42; and

(b) assigning said patient to one category in a clinical trial if said patient is determined to have a good prognosis, and a different category if that patient is determined to have a poor prognosis.

89. (New) A computer-implemented method for predicting a breast cancer patient as having a good prognosis or a poor prognosis, comprising:

classifying, on a computer, said patient as having a good prognosis or a poor prognosis based on a profile comprising measurements of levels of transcripts of, or proteins encoded by, respective genes in a plurality of genes in a cell sample taken from said patient, said plurality of genes comprising at least two of the genes for which markers are listed in

(b1) Table 1 if said patient has been classified as ER<sup>-</sup>, sporadic;

(b2) Table 2 if said patient has been classified as ER<sup>-</sup>, *BRCAl*;

(b3) Table 3 if said patient has been classified as ER<sup>+</sup>, ER/AGE high;

(b4) Table 4 if said patient has been classified as ER<sup>+</sup>, ER/AGE low, LN<sup>+</sup>; or

(b5) Table 5 if said patient has been classified as ER<sup>+</sup>, ER/AGE low, LN<sup>-</sup>,

wherein ER<sup>+</sup> designates a high ER level and ER<sup>-</sup> designates a low ER level, wherein said ER/AGE is a metric of said ER level relative to the age of said patient, and wherein LN<sup>+</sup> designates a greater than 0 lymph nodes status in said patient and LN<sup>-</sup> designates a 0 lymph nodes status in said patient.

90. (New) A method for assigning a breast cancer patient to one of a plurality of categories in a clinical trial, comprising:

(a) determining if said person has a good prognosis or a poor prognosis using the method of claim 89; and

(b) assigning said patient to one category in a clinical trial if said patient is determined to have a good prognosis, and a different category if that patient is determined to have a poor prognosis.

91. (New) The method of claim 89, wherein said classifying is carried out by a method comprising comparing said profile to a good prognosis template and/or a poor prognosis

template, and wherein said patient is classified as having a good prognosis if said profile has a high similarity to a good prognosis template or has a low similarity to a poor prognosis template or as having a poor prognosis if said profile has a low similarity to a good prognosis template or has a high similarity to a poor prognosis template, said good prognosis template comprising measurements of levels of transcripts of, or proteins encoded by, respective genes in said plurality of genes that are representative of levels of transcripts of, or proteins encoded by, said genes in a plurality of good outcome patients and said poor prognosis template comprising measurements of levels of transcripts of, or proteins encoded by, respective genes in said plurality of genes that are representative of levels of transcripts of, or proteins encoded by, said genes in a plurality of poor outcome patients, wherein a good outcome patient is a breast cancer patient who has non-reoccurrence of metastases within a first period of time after initial diagnosis and a poor outcome patient is a breast cancer patient who has reoccurrence of metastases within a second period of time after initial diagnosis.

92. (New) The method of claim 91, wherein said profile is an expression profile comprising measurements of a plurality of transcripts in a sample derived from said patient, wherein said good prognosis template comprises measurements of said plurality of transcripts that are representative of expression levels of said transcripts in said plurality of good outcome patients, and wherein said poor prognosis template comprises measurements of said plurality of transcripts that are representative of expression levels of said transcripts in said plurality of poor outcome patients.

93. (New) The method of claim 92, wherein measurement of each said transcript in said good prognosis template is an average of expression levels of said transcript in said plurality of good outcome patients.

94. (New) The method of claim 89, wherein said ER/AGE is classified as high if said ER level is greater than  $c \cdot (AGE - d)$ , and wherein said ER/AGE is classified as low if said ER level is equal to or less than  $c \cdot (AGE - d)$ , wherein  $c$  is a coefficient, AGE is the age of said patient, and  $d$  is an age threshold.

95. (New) The method of claim 89, wherein said individual has been classified as ER<sup>-</sup>, sporadic, and said plurality of genes comprises at least two of the genes for which markers are listed in Table 1.

96. (New) The method of claim 89, wherein said individual has been classified as ER<sup>-</sup>, sporadic, and said plurality of genes comprises all of the genes for which markers are listed in Table 1.

97. (New) The method of claim 89, wherein said individual has been classified as ER<sup>-</sup>, *BRCA1*, and said plurality of genes comprises at least two of the genes for which markers are listed in Table 2.

98. (New) The method of claim 89, wherein said individual has been classified as ER<sup>-</sup>, *BRCA1*, and said plurality of genes comprises all of the genes for which markers are listed in Table 2.

99. (New) The method of claim 89, wherein said individual has been classified as ER<sup>+</sup>, ER/AGE high, and said plurality of genes comprises at least two of the genes for which markers are listed in Table 3.

100. (New) The method of claim 89, wherein said individual has been classified as ER<sup>+</sup>, ER/AGE high, and said plurality of genes comprises all of the genes for which markers are listed in Table 3.

101. (New) The method of claim 89, wherein said individual has been classified as ER<sup>+</sup>, ER/AGE low, LN<sup>+</sup>, and said plurality of genes comprises at least two of the genes for which markers are listed in Table 4.

102. (New) The method of claim 89, wherein said individual has been classified as ER<sup>+</sup>, ER/AGE low, LN<sup>+</sup>, and said plurality of genes comprises all of the genes for which markers are listed in Table 4.

103. (New) The method of claim 89, wherein said individual has been classified as ER<sup>+</sup>, ER/AGE low, LN<sup>-</sup>, and said plurality of genes comprises at least two of the genes for which markers are listed in Table 5.

104. (New) The method of claim 89, wherein said individual has been classified as ER<sup>+</sup>, ER/AGE low, LN<sup>-</sup>, and said plurality of genes comprises all of the genes for which markers are listed in Table 5.